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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER	
BAGGOT, BRENDAN O	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,283	SPANGENBERG ET AL.	
	Examiner	Art Unit	
	Brendan O. Baggot	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *5,6,9,10,12,13,15,16 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,11,14,17,23 and 24* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Office Action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction / Election

The Office acknowledges the receipt of Applicant's restriction election, filed 4/23/07. Applicant elects Group I, claims 1-4, 7-8, 11, 14, 17, 23 and SEQ ID NO: 3 with traverse stating primarily that SEQ ID NO: 3 is contained within the non-identical SEQ ID NO: 2, Group II is merely a subset of Group I because Group I requires any coding sequence while Group II requires only a sequence which down regulates expression of pollen-specific antigen and that the search would be the same and thus there would be no burden to search I and II together. Applicant does not traverse the restriction of Group III from Groups I and II.

Applicant's traversal is unpersuasive for the following reasons: individual sequences are deemed to be independent inventions rather than species of a genus; Patent Office resources prohibit the searching of multiple sequences against the various databases in a single application; while a search of the prior art for one group may overlap with that of another group, they are not co-extensive of each other and thus would represent undue burden on Office resources.

Claims 5-6, 9-10, 12-13, 15-16, 18-22 are nonelected. Claim 1-4, 7-8, 11, 14, 17, 23 and new claim 24 correspond to Group I and are examined in the instant application.

This restriction is deemed proper and made FINAL.

Sequence Listing

1. Applicant's computer readable format sequence listing has been entered.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate. *See* MPEP 201.11, MPEP 601(I).

3. The abstract of the disclosure is objected to because it is not on a separate page. Correction is required. *See* M.P.E.P. § 608.01(b).

Drawings

4. The drawings are acceptable for examination.

Information Disclosure Statement

5. An initialed and dated information disclosure statement (IDS) which was submitted on 5/16/07, 1/11/07 is provided.

Claim Objections

6. Claims 1, 5 and 24 are objected to because of the following informalities: the claims recite nonelected sequences. Appropriate correction is required.

7. Claim 17 is an incomplete method claim in that it fails to achieve its stated objective.

8. In claims 1-4 it is suggested Applicant amend "an" to "the" nucleotide sequence for proper antecedence.

9. In claims 7, 11, 14, 17, 23 it is suggested Applicant amend "a" to "the" nucleic acid molecule for proper antecedence.

Written Description

10. Claims 1-4, 7-8, 11, 14, 17, 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines.

The claims are drawn to a sequence, SEQ ID NO: 3, a method that employs undescribed modified plants, cells, seeds, as well as undescribed heterologous nucleic acid sequences encoding wild-type or mutant 952bp *Lol* p 2 promoter production in a plant, and transgenic plants by said method. Said sequences include genes encoding wild-type or mutant 952bp *Lol* p 2 promoter from any source or a variant or fragment thereof (Claim 1), as well as any sequence from any source encoding any product which somehow "modulates" pollen-specific expression or activity of any gene from any source of any length and sequence (Claims 1-4). In contrast, Applicant has only described a 952 bp SEQ ID NO: 3, tobacco(dicot) transformation therewith (Example 3; page 18, line 21), and pollen specific expression of SEQ ID NO: 3 driving GUS (Example 4, page 19, lines 10-21).

Applicant has not described the structure or any other relevant characteristics for all nucleic acid sequences which would hybridize to or are a "modification" of 952bp *Lol* p 2 promoter in a plant and a literature review does not indicate that they are well known to one of skilled in the art. Applicant has only described nucleic acid sequences encoding SEQ ID NO: 3 from perennial ryegrass (*Lolium perenne* L.).

The Federal Circuit has clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *See also Fiddes v. Baird*, 30 USPQ2d 1481 (Bd. Pat. App. & Int. 1993). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Eli Lilly*. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. *See* The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 U.S.C. §112, first paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4, 7-8, 11, 14, 17, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 3, does not reasonably provide enablement for a sequence which hybridizes to SEQ ID NO: 3 under conditions of unspecified stringency, a complement, a fragment or variant, a "portion", a sequence 95% identical to SEQ ID NO: 3, or a nucleic acid having a size of at least 100 nucleotides of SEQ ID NO: 3, any of which are capable of modifying pollen-specific expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The *Wands* court set forth the enablement balancing test:

> Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims."

M.P.E.P. § 2164.01(a); *See also Ex Parte Forman* 230 USPQ 546, 547 (BdPatAppInt 1986); *See also Enzo Biochem, Inc., v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999).

Applicant's claims are broadly drawn to SEQ ID NO:3; a sequence which hybridizes to SEQ ID NO:3 under moderately or high stringency conditions; a complement; a fragment; a variant, a portion, or a sequence 95% identical thereto or a fragment or variant at least 100 nucleotides long wherein said molecule is capable of modifying pollen-specific expression, "modified . . . expression, " and any chimeric gene.

Applicants teach a 952 bp SEQ ID NO: 3, tobacco(dicot) transformation therewith (Example 3; page 18, line 21), and pollen specific expression of SEQ ID NO: 3 driving GUS (Example 4, page 19, lines 10-21).

Applicants do not teach a sequence which hybridizes to SEQ ID NO:3 under moderate or high stringency conditions; a complement, fragment, variant, or portion of SEQ ID NO: 3, or a sequence 95% identical thereto; a fragment or variant at least 100 nucleotides long and wherein said molecules are capable of modifying pollen-specific expression. Applicants do not teach any chimeric gene of any length and sequence from any source

Applicant has not taught a molecule capable of "modifying" pollen-specific expression of an operably linked gene of interest. Applicants have taught pollen-specific expression of GUS. But because GUS is not naturally present or expressed in pollen, Applicants could not and did not teach modified pollen-specific expression.

Furthermore, Applicants have only taught SEQ ID NO: 3 driven expression of GUS. Applicants have not taught any sequence from any source with any expression pattern other than SEQ ID NO: 3, or any sequence with a temporal profile, expression strength, or tissue specificity different from SEQ ID NO: 3.

Applicants do not teach a sequence a fragment or variant of SEQ ID NO:3 at least 100 nucleotides long and wherein said molecules retain pollen-specific expression promoter activity.

The Unpredictability of the Art and the State of the Prior Art

The state-of-the-art is such that one of skill in the art cannot predict which variants, portions, sequences which hybridize under moderate or high stringency, complements or sequences with 95% identity to SEQ ID NO: 3 will retain activity. There is abundant prior art to suggest that promoter identification and modification are difficult, unpredictable and unsuccessful. Recent reviews by Kim, Hannenhalli, Hauschild, Maiti, and by Doelling detail a variety of problems seen in promoter identification and modification.

The state of the prior art, as exemplified by Kim et al (Plant Molecular Biology, vol. 24, pp. 105-117, 1994)) teaches the extreme sensitivity of promoter regions to single base pair changes, the absolute requirement for as few as 3 to 6 nucleotides for promoter function, and the failure of a promoter to function either constitutively or specifically when lacking oligonucleotide regions approximately 100 bp upstream of the transcription start site (page 106, paragraph bridging the columns; paragraph bridging

pages 107 and 108; page 110, paragraph bridging the columns). In addition, the claimed nucleic acid sequence that is a functional fragments/variants thereof, sequences natively associated with SEQ ID NO: 3 would comprise non- functional transcriptional and translational elements, i.e. modifications of CAAT, TATA and the ATG codon, required for proper initiation of these cellular activities, known in the prior art; as well as highly conserved promoter regions rendered inactive by modifications. In addition, Applicant has not shown that a complement of SEQ ID NO: 1 can also have the desired promoter activity.

A recent review by Hannenhalli (2001) Bioinformatics 17: S90-S96) teaches that prediction of eukaryotic promoters has been one of the most elusive problems despite considerable effort devoted to the study. (*See* the abstract at least). In the instant case of a promoter, Hannenhalli's review teaches a 50% failure in the sensitivity of promoter detection (p. S90, last full sentence).

Hauschild et al (1998) Plant Molecular Biology, vol. 36, pp. 473-478) teaches that identification of promoters is highly unpredictable and that there was an unexpectedly high species specificity of poppy alkaloid pathway regulatory regions. Hauschild found that the berberine bridge enzyme (BBE1) promoter, when operably linked to GUS, was active in only 2 out 28 plant species tested and was only able to determine this after undue trial and error experimentation. (See Table 2, Abstract, page 477, right column, first full paragraph). Positive control 35S – GUS constructs showed notably different results. *Id.* Thus, promoters, including promoters such as SEQ ID NO: 3 – the p952 promoter – are difficult to identify, and identification is unpredictable because even if

one had the sequence of the entire ryegrass genome, including all the promoters, when put into a model system, the skilled artisan would not see any expression in many plants and thus would not discover that the ryegrass DNA region of interest contained or was a promoter. The skilled artisan would have to depend on luck that he uses the right model system. Interestingly, Hauschild found *no expression* in tobacco, the model system used by Applicants, using the BBE1 promoter.

Portions, fragments, complements, variants, sequences which hybridize under moderate or high stringency, or sequences with 95% identity to SEQ ID NO: 3 or variants of a DNA fragment that has promoter activity, including DNA polynucleotides with 95% identity to said portions, fragments, or variants of a DNA fragment, including portions which are a single base pair long, cannot predictably be assumed to also have promoter activity. Deletion analysis of various promoters have shown that even DNA segments from the portion of a promoter region containing sequence elements thought to be most important (*e.g.*, the TATA-box) need to be longer than 20 basepairs. Maiti et al, in studies on a figwort mosaic virus promoter, found that the smallest portion upstream of the transcriptional start site that would support transcription was 198 basepairs long; segments of 73 and 37 basepairs did not work (1997, Transgen. Res., 6:143-156, see Fig. 4). Doelling et al found that the minimal rRNA promoter of *Arabidopsis thaliana* is at least 33 nucleotides long (1995, Plant J. 8:683-692, see Fig. 1).

With regard to sequences having less than 100% sequence identity, the breadth of these claims encompasses unspecified base substitutions, deletions, additions,

insertions, and combinations thereof and promoters lacking a CAAT, TATA or ATG codon. One skilled in the art would not be able to predictably and reliably determine which sequences within the 95% sequence identity limitation would have the claimed activity other than by undue trial and error, or how inoperable embodiments can be readily eliminated without undue experimentation. Moreover, while one skilled in the art can readily make mutations to these two sequences, further guidance is needed as to what mutations would not ablate promoter function. Applicant provided no working example of any sequences within the claimed scope that has the asserted activity.

Guidance in the Specification

The specification, while suggesting the use of the SEQ ID NO: 3, did not provide significant guidance on how to overcome art recognized problems in achieving expression of promoter "portions" of DNA smaller, including single base pair polynucleotide promoters, how to achieve modified expression such as for example a modified temporal expression profile other than that of SEQ ID NO: 3, or how to make variants of SEQ ID NO: 3 while still retaining activity.

In addition, since the working examples disclosed in the specification are limited to unmodified SEQ ID NO: 3, the pollen-specific activity by said unmodified sequences cannot be extrapolated to any portion, fragment or variant thereof, absent specific guidance. While Applicant is not required to exemplify each and every claimed embodiment, specific guidance as to which region of the disclosed sequences can be modified, truncated so that the seed-specific promoter activity is retained is required.

The specification has no working examples of sequences other than SEQ ID NO: 3, no working examples of sequences which comprise at least 100 nucleotides of SEQ ID NO: 3 and 95% sequence identity thereto.

In addition, the claimed nucleic acid sequence that is a portion/fragment/variant/complement/hybridizant of SEQ ID NO: 3 would encompass non-functional transcriptional and translational elements, i.e. modifications of CAAT, TATA and the ATG codon which are known in the prior art to be required for proper initiation of these cellular activities, as well as highly conserved promoter regions rendered inactive by modifications. In addition, Applicant has not shown that a complement of SEQ ID NO: 3 can also have the desired promoter activity.

In addition, since the lone working example disclosed in the specification is limited to SEQ ID NO: 3, the regulatory region activity by said sequence cannot be extrapolated to any portion/fragment/variant/complement/hybridizant thereof, absent specific guidance. This is particularly so in light of the teachings of Hauschild set forth hereinabove.

Further, Applicant has not provided guidance for how to identify alterations, insertions, or additions which would be tolerated and no guidance on what the various promoter elements responsible for SEQ ID NO: 3 activity are. While Applicant is not required to exemplify each and every claimed embodiment, specific guidance as to which region of the disclosed sequences can be modified or substituted so that the SEQ ID NO: 3-specific promoter activity is retained is required. Absent such guidance, one

skilled in the art would not be able to make the claimed nucleic acid sequences without undue experimentation.

Without sufficient guidance, determination of variants, portions, fragments of SEQ ID NO: 3, and without guidance on how to overcome the loss of promoter activity seen in random modifications of promoters to be used in transgenic plants, it is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. *See In re Wands*, 858 F.2d 731,8 USPQ2nd 1400 Fed. Cir, 1988)

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue trial and error experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. §102.

12. Claims 1-4, 7-8, 11, 14, 17, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh, et al (US 6,180,368, 2001). As written, claim 1 is drawn to an

isolated polynucleotide comprising SEQ ID NO: 3. "Portion", "variant" or fragments thereof is interpreted to include a single nucleotide base pair.

Singh, et al teaches an isolated and purified polynucleotide sequence from ryegrass, *Lolium perenne,* (*See* Claim 2-5; see SEQ ID NO: 1, 3, 5) that shares at least one nucleotide base pair (see SEQ ID NO: 1, 3, 5, e.g.) with instant SEQ ID NO: 3, of at least one base pair operably linked to a second nucleic acid molecule (*See* column 2, lines 39-43), complement (*See* Claim 2), hybridizant (*See* Claim 11; column 9, line 24 e.g.), portion (*See* Claim 2; column 9, line 30 e.g.), "variant" (*See* abstract, Claim 5) or fragments thereof (*See* Claim 5, 7) which would be complementary to one base of a polynucleotide encoding SEQ ID NO:3, and which would have 100% identity to thereto, and recombinant plants transformed therewith (column 3, lines 37-54, e.g.) and as such, Singh, et al anticipates the claimed invention, and therefore the claims stand rejected.

Because the claim reads on a single base pair, the percent identity of the Sing sequence with the instant sequence is 100%.

Claim Rejections - 35 U.S.C. §112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 1 is rejected under 35 U.S.C. §35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

> "Moderately stringent conditions" or "high stringency conditions" for hybridization may be identified as described by Sambrook *et al*, 1989, the relevant disclosure of which is incorporated herein by reference.
>
> Such conditions are readily determinable by a person skilled in the art, and are generally an empirical calculation based on probe length, salt concentration and washing temperature. For example, the use of a washing solution including approximately 0.7 to approximately 0.2 x SSC (standard sodium citrate), at approximately 50°C to approximately 60°C, would generally be considered moderately stringent conditions. For example, the use of a washing solution including approximately 0.2 to approximately 0.1 x SSC at approximately 60°C to approximately 70°C would generally be considered high stringency conditions.

(*See* page 5 in the Specification).

Regarding applicant's recitation of "moderately stringent or high stringency conditions", it is unclear what is encompassed by "moderately stringent or high stringency conditions" since skilled artisans can and do define stringency conditions differently and Applicant has not properly defined "stringency conditions" but instead provided only examples. (*See* page 5 of the Specification).

Regarding applicant's recitation of "complement", it is unclear whether "complement" is intended to be fully complementary or whether a short sequence, such as a single base pair would be encompassed by Applicant's recitation of "complement". (*See* Specification).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitations complement, "portion," "hybridizes under stringent conditions," and the claim also recites SEQ ID NO: 3 which is the narrower statement of the range/limitation.

Clarification and/or correction are required.

Remarks

14. Claim 24 drawn to an isolated SEQ ID NO: 3 is deemed free of the prior art in light of the failure of the prior art to teach or reasonably suggest SEQ ID NO: 3. For SEQ ID NO: 3, the closest prior art identified through sequence searches was OLEK, et al., 6.8% identical, found in IDENTITY_NUC Database, US-10-311-455-1048 from PCT/EP01/07537, published on 03.01.2002.

15. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brendan O. Baggot
Patent Examiner
Art Unit 1638

David T. Fox
Primary Examiner
Art Unit 1638

bob

Appendix A

SCORE Search Results Details for Application 10561283 and Search Result 20070221_171904_us-10-561-283-3.rnpm.
Score Home Page Retrieve Application List SCORE System Overview SCORE FAQ Comments / Suggestions

This page gives you Search Results detail for the Application 10561283 and Search Result 20070221_171904_us-10-561-283-3.rnpm.

Go Back to previous page

GenCore version 6.2

OM nucleic - nucleic search, using sw model

Run on: February 22, 2007, 22:30:09 ; Search time 6830 Seconds
(without alignments)
8156.804 Million cell updates/sec

Title: US-10-561-283-3
Perfect score: 953
Sequence: 1 agcttgggaccgtcaagttg.....aaccatccaacaaatccaga 953

Scoring table: IDENTITY_NUC
Gapop 10.0 , Gapext 1.0

Searched: 86534536 seqs, 29229259966 residues

Total number of hits satisfying chosen parameters: 173069072

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

	Result No.	Score	% Query Match	Length	DB	ID	Description
	1	953	100.0	953	51	US-10-561-283-3	Sequence 3, Appli
	2	953	100.0	2789	51	US-10-561-283-2	Sequence 2, Appli
	3	953	100.0	3356	51	US-10-561-283-1	Sequence 1, Appli
	4	69.4	7.3	1112	27	US-09-627-937B-53	Sequence 53, Appl
	5	65.2	6.8	963	42	US-10-266-090-10200	Sequence 10200, A
	6	65.2	6.8	10254	48	US-10-311-455-1048	Sequence 1048, Ap
c	7	63.2	6.6	962	23	US-09-406-292A-436	Sequence 436, App
c	8	61.6	6.5	493	32	US-09-837-604A-18338	Sequence 18338, A
c	9	61.6	6.5	493	32	US-09-837-604B-18338	Sequence 18338, A
c	10	61.6	6.5	493	78	US-60-197-872-11235	Sequence 11235, A
	11	60.8	6.4	7046	48	US-10-311-455-2090	Sequence 2090, Ap
c	12	60.6	6.4	1035	42	US-10-266-090-12300	Sequence 12300, A
c	13	60.4	6.3	1599662	36	US-09-947-911-108	Sequence 108, App
	14	59.2	6.2	1072	42	US-10-266-090-27663	Sequence 27663, A
c	15	59.2	6.2	2300	86	US-60-762-056-24932	Sequence 24932, A
c	16	58.8	6.2	500	23	US-09-474-435A-107	Sequence 107, App
c	17	58.2	6.1	1201	42	US-10-266-090-18309	Sequence 18309, A
	18	57.8	6.1	9180	48	US-10-311-455-1938	Sequence 1938, Ap
	19	57.6	6.0	990	45	US-10-301-480A-295361	Sequence 295361,
	20	57.6	6.0	990	46	US-10-301-480B-295361	Sequence 295361,
	21	57.6	6.0	990	47	US-10-301-480C-295361	Sequence 295361,
c	22	57.6	6.0	8056	50	US-10-473-126-386	Sequence 386, App
c	23	57.6	6.0	184475	80	US-60-243-468-477	Sequence 477, App
c	24	57.6	6.0	184475	80	US-60-243-742-76	Sequence 76, Appl
	25	57.6	6.0	2307596	36	US-09-948-128-334	Sequence 334, App
c	26	57.6	6.0	8616041	36	US-09-947-916-174	Sequence 174, App
	27	57.4	6.0	557	32	US-09-865-419A-40437	Sequence 40437, A
	28	57.4	6.0	557	79	US-60-208-063-23493	Sequence 23493, A
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c	33	57.2	6.0	7928029	36	US-09-947-916-16	Sequence 16, Appl
c	34	56.8	6.0	358	28	US-09-654-617-340563	Sequence 340563,
c	35	56.8	6.0	358	28	US-09-684-016-340563	Sequence 340563,
c	36	56.8	6.0	358	78	US-60-145-485-7541	Sequence 7541, Ap
c	37	56.6	5.9	943	45	US-10-301-480A-213669	Sequence 213669,
c	38	56.6	5.9	943	46	US-10-301-480B-213669	Sequence 213669,
c	39	56.6	5.9	943	47	US-10-301-480C-213669	Sequence 213669,
	40	56.4	5.9	1026	42	US-10-266-090-30279	Sequence 30279, A
c	41	56.4	5.9	1143	74	US-11-360-355-43297	Sequence 43297, A
c	42	56.4	5.9	1143	85	US-60-655-875-43297	Sequence 43297, A
	43	56.2	5.9	502	52	US-10-621-901-2065	Sequence 2065, Ap
	44	56.2	5.9	502	52	US-10-621-901-2070	Sequence 2070, Ap
	45	56.2	5.9	502	81	US-60-319-414-2065	Sequence 2065, Ap

ALIGNMENTS

RESULT 6
US-10-311-455-1048
; Sequence 1048, Application US/10311455
; GENERAL INFORMATION:
; APPLICANT: OLEK, Alexander
; APPLICANT: PIEPENBROCK, Christian
; APPLICANT: BERLIN, Kurt
; TITLE OF INVENTION: Diagnosis of Diseases Associated with the Immune System by Determining
; TITLE OF INVENTION: cytosine methylation
; FILE REFERENCE: 5013.1014
; CURRENT APPLICATION NUMBER: US/10/311,455
; CURRENT FILING DATE: 2002-12-16
; PRIOR APPLICATION NUMBER: PCT/EP01/07537
; PRIOR FILING DATE: 2001-07-02
; PRIOR APPLICATION NUMBER: DE 10032529.7
; PRIOR FILING DATE: 2000-06-30
; PRIOR APPLICATION NUMBER: DE 10043826.1
; PRIOR FILING DATE: 2000-09-01
; NUMBER OF SEQ ID NOS: 2424
; SEQ ID NO 1048
; LENGTH: 10254
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: chemically treated genomic DNA (Homo sapiens)
; FEATURE:
; NAME/KEY: unsure
; LOCATION: 5274, 6551, 9520
; OTHER INFORMATION: n is a or g or c or t
US-10-311-455-1048

Query Match 6.8%; Score 65.2; DB 48; Length 10254;
Best Local Similarity 53.5%; Pred. No. 5.6e-07;
Matches 136; Conservative 0; Mismatches 118; Indels 0; Gaps 0;

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